UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re SANOFI-AVENTIS SECURITIES LITIGATION	:	Civil Action No. 1:07-cv-10279-GBD
	:	CLASS ACTION
This Document Relates To:	:	
ALL ACTIONS.	:	

FIRST AMENDED COMPLAINT FOR VIOLATION OF SECURITIES LAWS

INTRODUCTION AND OVERVIEW

1. Lead Plaintiffs, City of Edinburgh Council of the Lothian Pension Fund and New England Carpenters Guaranteed Annuity Funds (collectively referred to as "plaintiffs"), on behalf of themselves and all other persons similarly situated, allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys.

NATURE OF THE ACTION

2. This is a federal securities class action brought against sanofi-aventis SA ("Sanofi" or the "Company") and certain of its officers for violations of the Securities Exchange Act of 1934 (the "Exchange Act"). This action is brought on behalf of: (a) all United States-based purchasers of Sanofi securities on the New York Stock Exchange ("NYSE"); (b) all United States-based purchasers of Sanofi securities on any foreign exchange; and (c) all foreign purchasers of Sanofi securities on the NYSE, during the period February 20, 2006 through June 13, 2007 (the "Class Period"), who were damaged as a result of defendants' violations of federal securities laws.

3. This action concerns defendants' misleading statements and material omissions regarding the development of the drug rimonabant and Sanofi's New Drug Application ("NDA") filed with the United States Food and Drug Administration ("FDA") for the use and promotion of rimonabant as treatment for obesity in the United States. Sanofi marketed rimonabant as "Acomplia" in Europe until it was banned in early 2009, and proposed marketing the drug under the trade name "Zimulti" in the United States.

4. Rimonabant is classified as a Cannaboid 1 ("CB-1") Receptor Antagonist/Inverse Agonist. In lay terms, the compound directly affects the brain's hunger signal – thereby reducing the craving for food. Prior to the Class Period, defendants conducted four phase III trials of

rimonabant's efficacy and safety in treating obesity, also known as the Rimonabant In Obesity studies ("RIO Studies"). Prior to the Class Period, the Company had also completed at least eight additional clinical studies of rimonabant as a treatment for other indications, including alcoholism, schizophrenia and smoking. By the time Sanofi completed those studies, the Company had invested several years and millions of dollars to develop the drug and prepare it for marketing in the United States and around the globe.

5. As a CB-1 receptor drug that acts directly on the brain's hunger signal, as opposed to compounds that act as mere stimulants (*e.g.*, Fen-Phen), rimonabant was considered to be a "first-in-class" weight-loss drug. Accordingly, prior to and throughout the Class Period, defendants positioned rimonabant in the United States as the first "magic pill" that would help people shed pounds without serious side effects. Had defendants' claims been true and the FDA approved the drug for use in the United States, Sanofi was set to reap an astronomical windfall. During the Class Period, analysts estimated Sanofi's annual sales of rimonabant could exceed €3.2 billion by 2011.

6. Defendants submitted the NDA for rimonabant to the FDA in April 2005. The NDA reported only one case of suicidal ideation[1] in patients participating in the rimonabant trials, and that patient had been taking placebo, not rimonabant. When the FDA subsequently asked for further information about suicidality in the rimonabant trials, however, Sanofi produced records of several additional cases of suicidal ideation that had not been initially reported in the NDA. These records showed a "signal" of suicidality for those patients taking rimonabant. Per the World Health Organization ("WHO"), a "signal" in drug studies is defined as "reported information on a possible

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[1] "Suicidal ideation" is a term of art used to categorize a range of suicidal thoughts from fleeting suicidal feelings to the planning of a suicide attempt.

causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously."

7. As a result of the signal between rimonabant and suicidality, on February 17, 2006, the FDA sent defendants a letter asking them to reassess the database from the rimonabant trials to investigate the link between the drug and "suicidality," a term of art used to describe both suicidal thoughts and behaviors. As the FDA put it, "***review of the preclinical and clinical data raised concern about associations between rimonabant and increased frequencies of psychiatric adverse events, including suicidality.***" The FDA further directed Sanofi to obtain a formal, independent assessment of the link between rimonabant and suicidality from Dr. Kelly Posner at Columbia University.

8. Dr. Posner reviewed a narrative for each patient in the clinical studies of rimonabant who had reported a neuropsychiatric event. The narratives were "blinded," meaning that Dr. Posner did not know at the outset which patients had been taking rimonabant and which placebo. Dr. Posner assessed the narratives using the Columbia Classification Algorithm of Suicide Assessment ("C-CASA"), which she had helped to develop, in order to evaluate them for evidence of suicidality.

9. During this period, defendants publicly disclosed the receipt of the FDA's letter and positively asserted that "no additional trial in obesity has been requested by the agency." Defendants kept investors in the dark, however, regarding the FDA's concerns about suicidality and the independent assessment of suicidality that the FDA had required. Although there is always uncertainty regarding FDA approval of a new drug, after receiving the FDA's letter defendants knew that a specific, material risk to rimonabant's approval had materialized and failed to disclose it. Instead, they continued to tell investors that United States sales of rimonabant would launch in the second half of 2006, leading investors to believe that there had been no material change to the

likelihood of FDA approval. Investors could not adequately assess the viability of Sanofi's application without knowing about the FDA's concerns and the critical suicidality analysis that was ongoing. Nonetheless, defendants misleadingly assured investors "[y]ou know everything concerning rimonabant."

10. Defendants submitted Dr. Posner's suicidality assessment to the FDA on October 26, 2006. The assessment showed a definite link between rimonabant and suicidality, with many more patients taking rimonabant developing suicidality than patients taking placebo.[2] Indeed, the link between rimonabant and suicidality was statistically significant, with the risk of suicidality doubling for those taking rimonabant.

11. Sanofi's application to the FDA for rimonabant was now in extreme peril. The very assessment that the FDA had demanded showed a statistically significant link between rimonabant and suicidality. Nonetheless, defendants continued to mislead investors. In one conference call, an analyst asked defendant Spek point-blank about the application for rimonabant: "Was additional data submitted?" Spek replied, "the approvable letter did not ask for new additional clinical trials, consequently it is easier for me to say that we have not submitted new data in this respect." It may have been easy to say, but it was entirely misleading. Just five days before the call, Sanofi had, in fact, submitted additional data to the FDA, namely Dr. Posner's assessment, which showed a link between rimonabant and suicidality.

12. Defendants told investors the good news about the FDA's letter, *i.e.*, that it did not ask Sanofi to conduct any new clinical trials of rimonabant. In contrast, defendants failed to disclose

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[2] Dr. Posner identified 91 patients that were definitely suicidal. Of those, almost three times as many patients taking rimonabant 20 mg experienced suicidal ideation compared to placebo.

the bad news, namely that the FDA was concerned about the link between rimonabant and suicidality and had demanded an independent, formal assessment of that link before the agency would take further action on the drug. Similarly, defendants spoke out when they had good news – boasting that they had supplemented their FDA application with the purportedly positive results of a rimonabant study called SERENADE – but failed to disclose the bad news, *i.e.*, that they had also supplemented their application with Dr. Posner's suicidality assessment, which showed a statistically significant link between rimonabant and suicidality.

13. Defendants also touted the positive results of several rimonabant studies but failed to disclose that more patients taking rimonabant in those studies suffered suicidality than those who took placebo. Time and again, defendants cherry-picked and disclosed those study results that supported the rimonabant NDA and hid results from the exact same studies that did not support it.

14. Regarding the RIO Studies of rimonabant, defendants stated "long term exposure did not identify new or increased risks." They also failed to disclose that Dr. Posner's analysis confirmed the existence of an increased and statistically significant risk of suicidality.

15. Defendants disingenuously claimed that they would not speculate about FDA approval, yet in the next breath said "we're simply waiting for registration in the United States. And this will come about sooner or later" and "we are extremely optimistic as to obtaining an NDA for Rimonabant." Such statements obligated defendants to disclose the material risk that the link between suicidality and rimonabant posed to the drug's application.

16. The Class Period ends on June 13, 2007, when the FDA held a meeting of its Endocrinologic and Metabolic Advisory Committee ("the Advisory Committee") regarding the rimonabant application. At that time, the FDA disclosed the suicidality information that defendants had submitted on October 26, 2006. The report prepared by the FDA for the Advisory Committee

stated unequivocally that, based on the data Sanofi had submitted to the agency, "***[c]ompared to placebo, 20 mg rimonabant statistically significantly increased suicidality*** . . . ." Indeed, several different tests confirmed the statistically significant link between rimonabant with suicidality. Based on the data Sanofi had submitted, the FDA representative at the meeting, Dr. Amy Egan, stated that the FDA "strongly" believed that rimonabant caused suicidality.

17. Sanofi made a number of presentations to the Advisory Committee. These presentations demonstrated that defendants knew that rimonabant's statistically significant link with suicidality imperiled the NDA. Sanofi's own briefing document contains an analysis of Dr. Posner's assessment showing over twice the incidence of suicidal ideation in patients taking rimonabant, with Sanofi conceding that "[a]n imbalance [between rimonabant and placebo] was seen . . . in suicidal ideation in the obesity studies . . . ." As a result of this "imbalance," and in an effort to save rimonabant, Sanofi proposed that the FDA direct doctors to screen out patients with a history of suicidality and not prescribe rimonabant for them. Sanofi further proposed issuing a medication guide to physicians acknowledging that "[i]n some patients [r]imonabant use has been associated with an increase in depression, anxiety and suicidal thoughts."

18. Largely because of the statistically significant link between rimonabant and suicidality, the FDA's Advisory Committee of experts unanimously recommended that the FDA deny Sanofi's application for rimonabant. In response, the prices of Sanofi's securities dropped sharply on and after June 13, 2007, causing investors untold losses. Following the FDA disclosure regarding suicidality, defendants withdrew Sanofi's application for rimonabant even before the FDA made its final decision. Subsequently, European regulators, who had previously approved rimonabant, banned sales of the drug.

THE PARTIES

Lead Plaintiffs

19. By Court Order dated February 29, 2008, the City of Edinburgh Council as Administering Authority of the Lothian Pension Fund ("Lothian Pension Fund") and New England Carpenters Guaranteed Annuity Fund ("New England Carpenters Fund") were appointed as Lead Plaintiffs in this action. The Lothian Pension Fund pays pensions to former employees of various city and regional councils, as well as other public sector organizations and is managed and administered in Edinburgh, United Kingdom. New England Carpenters Fund, managed and administered in Wilmington, Massachusetts, was established in 1981 and pays benefits to retired and disabled members. As set forth in the Certifications of the Lothian Pension Fund and New England Carpenters Fund, filed in connection with their motion to be appointed Lead Plaintiffs, they purchased Sanofi securities during the Class Period and, as a result of the defendants' conduct detailed herein, suffered damages in connection with the purchase of Sanofi securities.

Defendants

20. Sanofi's core business is the development and marketing of pharmaceuticals, with a focus on the therapeutic areas of thrombosis, cardiovascular, metabolic disorders, oncology, central nervous system and internal medicine. It is the third largest pharmaceutical company in the world. The Company was incorporated in France in 1994 as a *société anonyme* for a term of 99 years. In August 2004, Sanofi's predecessor, Sanofi-Synthélabo, took control of Aventis and changed its registered name to sanofi-aventis. In December 2004, the two companies merged and Sanofi was the surviving entity. Throughout the Class Period, Sanofi's American Depository Shares ("ADSs") traded on the NYSE and the Company's common stock traded on Euronext in Paris, France. In

addition, Sanofi's depository shares and depository receipts traded on other exchanges around the globe.

21. Defendant Jean-François Dehecq ("Dehecq") served as CEO of Sanofi through December 31, 2006. At all relevant times, Dehecq was the Chairman of the Board of the Company. As part of his duties as Chairman and CEO, Dehecq was responsible for monitoring and reporting to investors and the market on the status of Sanofi's pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi's Code of Ethics, Dehecq was charged with determining whether to disclose information that would likely affect the Company's stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi's Code of Ethics required that Dehecq keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Dehecq participated in the issuance of misleading statements and material omissions and failed to disclose the statistically significant link between rimonabant and suicidality. In addition to issuing statements throughout the Class Period, Dehecq repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) In conjunction with Sanofi's public financial statements filed with the SEC during the Class Period, Dehecq signed a certification pursuant to §302 of the Sarbanes-Oxley Act, attesting that he reviewed the contents of the filing to confirm the "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading." To assure that the certification was not simply a hollow gesture, Dehecq was required to and did further confirm that he, along with the Company's Principal Financial Officer ("PFO"), was responsible for

establishing and maintaining Sanofi's disclosure controls and procedures, had designed such controls to assure that material information relating to Sanofi's business was promptly made known to Dehecq and the Company's senior executives, and had routinely evaluated the effectiveness of the Company's policies to assure that he and other executives were made aware of material information. At no time during the Class Period did Dehecq or any other defendant assert that they were not aware of material aspects of the status and results of Sanofi's clinical trials and the NDA for the use of rimonabant as a treatment for obesity; and

(d) While CEO of Sanofi, Dehecq regularly visited the Company's United States offices in Bridgewater, New Jersey, to conduct "town-hall" meetings during which he discussed current news, business and sales and Sanofi's financial performance with United States employees. During the town-hall meetings, Dehecq personally presented information concerning rimonabant's development and regulatory posture to Sanofi employees.

22. Defendant Gérard Le Fur ("Le Fur") served as Senior Executive Vice President of Scientific and Medical Affairs until January 1, 2007, when he became CEO of the Company. As part of his duties at Sanofi, Le Fur was responsible for monitoring and reporting to investors and the market on the status of Sanofi's pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi's Code of Ethics, Le Fur was charged with determining whether to disclose information that would likely affect the Company's stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi's Code of Ethics required that Le Fur keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Le Fur participated in the issuance of misleading statements and material omissions and failed to disclose the statistically significant link between

rimonabant and suicidality. In addition to issuing statements throughout the Class Period, Le Fur repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) In conjunction with Sanofi's public financial statements filed with the SEC during the Class Period, Le Fur signed a certification pursuant to §302 of the Sarbanes-Oxley Act, attesting that he reviewed the contents of the filing to confirm the "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading." To assure that the certification was not simply a hollow gesture, Le Fur was required to and did further confirm that he, along with the Company's PFO, was responsible for establishing and maintaining Sanofi's disclosure controls and procedures, had designed such controls to assure that material information relating to Sanofi's business was promptly made known to Le Fur and the Company's senior executives and had routinely evaluated the effectiveness of the Company's policies with regard to assuring that he and other executives were made aware of material information. At no time during the Class Period did Le Fur or any other defendant assert that they were not aware of material aspects of the status and results of Sanofi's clinical trials and the NDA for the use of rimonabant as a treatment for obesity;

(d) From March 1, 2005 through December 31, 2006, Le Fur reported directly to defendant Dehecq; and

(e) Throughout the Class Period, Le Fur regularly visited the Company's United States offices in Bridgewater, New Jersey, to conduct "town-hall" meetings during which he discussed current news, business and sales and Sanofi's financial performance with United States employees. During the town-hall meetings, Le Fur personally presented information concerning rimonabant's development and regulatory posture to Sanofi employees.

23. Defendant Jean Claude Leroy ("Leroy") was, at all relevant times, the PFO and Sanofi's Executive Vice President of Finance and Legal. As part of his duties as PFO, Leroy was responsible for monitoring and reporting to investors and the market on the status of Sanofi's pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi's Code of Ethics, Leroy was charged with determining whether to disclose information that would likely affect the Company's stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi's Code of Ethics required that Leroy keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Leroy participated in the issuance of misleading statements and material omissions and failed to disclose that rimonabant caused depression and suicidal ideation as uncovered in the Company's clinical trials for the use of rimonabant for the treatment of obesity and other medical conditions. In addition to issuing statements throughout the Class Period, Leroy repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) In conjunction with Sanofi's public financial statements filed with the SEC during the Class Period, Leroy signed a certification pursuant to §302 of the Sarbanes-Oxley Act, attesting that he reviewed the contents of the filing to confirm the "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading." To assure that the certification was not simply a hollow gesture, Leroy was required to and did further confirm that he, along with the Company's CEO, was responsible for establishing and maintaining Sanofi's disclosure controls and procedures, had designed such controls to assure that material

information relating to Sanofi's business was promptly made known to Leroy and the Company's senior executives and had routinely evaluated the effectiveness of the Company's policies with regard to assuring that he and other executives were made aware of material information. At no time during the Class Period did Leroy or any other defendant assert that they were not aware of material aspects of the status and results of Sanofi's clinical trials and the NDA for the use of rimonabant as a treatment for obesity;

(d) From March 1, 2005 through December 31, 2006, Leroy reported directly to defendant Dehecq and from January 1, 2007 through the end of the Class Period, Leroy reported directly to defendant Le Fur; and

(e) Throughout the Class Period, Leroy regularly visited the Company's United States offices in Bridgewater, New Jersey, to conduct "town-hall" meetings during which he discussed current news, business and sales and Sanofi's financial performance with United States employees. During the town-hall meetings, Leroy personally presented information concerning rimonabant's development and regulatory posture to Sanofi employees.

24. Defendant Hanspeter Spek ("Spek") was, at all relevant times, Executive Vice President of Pharmaceutical Operations. As part of his duties at Sanofi, Spek was responsible for monitoring and reporting to investors and the market on the status of Sanofi's pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi's Code of Ethics, Spek was charged with determining whether to disclose information that would likely affect the Company's stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi's Code of Ethics required that Spek keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Spek participated in the issuance of misleading statements and material omissions and failed to disclose the statistically significant link between rimonabant and suicidality. In addition to issuing statements throughout the Class Period, Spek repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) Between March 1, 2005 and December 31, 2005, Spek reported directly to defendant Dehecq, and thereafter directly to defendant Le Fur; and

(d) Throughout the Class Period, Spek regularly visited the Company's United States offices in Bridgewater, New Jersey, to conduct "town-hall" meetings during which he discussed current news, business and sales and Sanofi's financial performance with United States employees. During the town-hall meetings, Spek personally presented information concerning rimonabant's development and regulatory posture to Sanofi employees.

25. Defendant Marc Cluzel ("Cluzel") was, at all relevant times, Senior Vice President of Development and Scientific Affairs. As part of his duties at Sanofi, Cluzel was responsible for monitoring and reporting to investors and the market on the status of Sanofi's pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi's Code of Ethics, Cluzel was charged with determining whether to disclose information that would likely affect the Company's stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi's Code of Ethics required that Cluzel keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Cluzel participated in the issuance of misleading statements and material omissions and failed to disclose that rimonabant caused depression and suicidal ideation as uncovered in the Company's clinical trials for the use of rimonabant for the

treatment of obesity and other medical conditions. In addition to issuing statements throughout the Class Period, Cluzel repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) Between March 1, 2005 and December 31, 2005, Cluzel reported directly to defendant Dehecq, and thereafter directly to defendant Le Fur; and

(d) Throughout the Class Period, Cluzel regularly visited the Company's United States offices in Bridgewater, New Jersey, to conduct "town-hall" meetings during which he discussed current news, business and sales and Sanofi's financial performance with United States employees. During the town-hall meetings, Cluzel personally presented information concerning rimonabant's development and regulatory posture to Sanofi employees.

26. Defendant Douglas Greene ("Greene") was, at all relevant times, Vice President of Development and Scientific Affairs and Chief Medical Officer of Sanofi-U.S. Sanofi appointed defendant Greene to the position of Chief Medical Officer specifically to launch rimonabant in the United States because of his previous experience with drug and approval process with respect to other drug agencies around the globe. As part of his duties at Sanofi, Greene was responsible for monitoring and reporting to investors and the market on the status of Sanofi's pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi's Code of Ethics, Greene was charged with determining whether to disclose information that would likely affect the Company's stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi's Code of Ethics required that Greene keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Greene participated in the issuance of misleading statements and material omissions and failed to disclose the statistically significant link between rimonabant and suicidality. In addition to issuing statements throughout the Class Period, Greene repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) Greene reported directly to defendant Le Fur; and

(d) Throughout the Class Period, Greene participated in "town-hall" meetings during which he discussed current news, business and sales and Sanofi's financial performance with United States employees. During the town-hall meetings, Greene personally presented information concerning rimonabant's development and regulatory posture to Sanofi employees.

JURISDICTION AND VENUE

27. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. §240.10b-5.

28. This Court has subject matter jurisdiction over the claims brought on behalf of United States-based investors who purchased or otherwise acquired Sanofi securities on the NYSE or any foreign exchange, and on behalf of all foreign purchasers who purchased or otherwise acquired Sanofi securities on the NYSE because:

(a) Defendants' wrongful conduct alleged herein had a substantial effect upon the United States markets, United States-based and foreign investors and the price of Sanofi's securities on the NYSE and foreign exchanges;

(b) Defendants' activities in the United States were more than merely preparatory to securities fraud conducted elsewhere and their activities or culpable failures to act within the United States directly caused plaintiffs' losses;

(c) The Company's ADSs trade on the NYSE and the Company files regular, periodic financial reports with and is subject to the jurisdiction of the SEC and, thus, the United States federal securities laws;

(d) Sanofi maintains a significant presence in the United States, which is a critical component of the Company's global business. Like many of Sanofi's drugs, the Company sought approval of rimonabant with the FDA so the drug could be marketed for various indications within the United States. The Company has thousands of employees throughout the United States. Sanofi retains sales force regional offices in the states of New York, Pennsylvania, Missouri, Atlanta, Texas and California. Sanofi maintains its United States central drug distribution facility in Des Plains, Illinois. The Company also maintains a drug manufacturing facility in Missouri as well as training facilities in New York;

(e) The defendants utilized the United States mails, interstate wires and the facilities of the United States securities exchanges in furtherance of the fraud alleged herein. Prior to and during the Class Period, Sanofi conducted numerous conference calls with analysts located in the United States. Defendants Dehecq, Le Fur, Spek, Leroy and Cluzel conducted conference calls in the United States (including in New York City) and met in person with analysts and investors located in the United States. Furthermore, during the Class Period, the individual defendants knew they were disseminating materially misleading information to shareholders residing throughout the United States; and

(f) The defendants have extensive contact with the United States regulatory agencies, such as the FDA and the United States Patent and Trademark Office regarding the promotion, manufacturing and patenting of their pharmaceutical products within the United States, including the ill-fated rimonabant.

29. This Court may exercise personal jurisdiction over each individual defendant because each has availed himself of the privileges and protection of the laws of the United States and its several states, and this litigation arises out of each individual defendant's contacts with the United States. The individual defendants caused Sanofi to litigate patent cases in federal courthouses throughout the United States to protect the Company's revenue streams from generic competition. In fact, in August 2006, the individual defendants caused Sanofi to seek a preliminary injunction in this very district, which the Court granted, in order to stop the sales of generic Plavix. During the Class Period, the individual defendants regularly traveled to various locations within the United States on Sanofi business. Defendants Dehecq, Le Fur, Spek and Leroy were present in New York City during the Class Period for the purpose of participating in an analyst-and-investor conference. The individual defendants signed quarterly or annual reports on Forms 6-K and 20-F, which were filed with the SEC and contained alleged misrepresentations and/or omissions and each individual defendant caused the dissemination of false and misleading reports and statements to Sanofi investors in the United States. Each individual defendant knew that Sanofi's securities traded in the United States. Each individual defendant knew that the Company's press releases were disseminated in the United States, that the Company regularly filed reports with the SEC and that United States investors would rely upon the information contained in the reports and releases. Each individual defendant engaged in a course of unlawful conduct that had an effect in the United States, regardless of where such conduct occurred, by influencing United States investors and foreign investors who invested in Sanofi securities traded in the United States. These United States-based effects were both the direct and foreseeable results of the individual defendants' unlawful conduct as alleged herein.

30. Venue is proper in this district pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b). Many of the acts and transactions giving rise to the violations of law complained of herein occurred in substantial part in this district. Sanofi's ADSs trade on the NYSE, which is located in this district, and the Company markets and sells its pharmaceutical products within this district.

Defendants' Knowledge/Access to the Suicidality Information Regarding Rimonabant

31. Throughout the Class Period, the individual defendants held themselves out to investors and the market as the persons most knowledgeable at Sanofi about the Company's drug pipeline, NDA submissions and safety data associated with Sanofi clinical trials. As described more fully in ¶¶21-26, each of the individual defendants held one of the most senior positions at Sanofi with responsibility for deciding what information concerning the Company's drugs should be disclosed to investors and, in accordance with Sanofi's Code of Ethics, were charged with keeping themselves informed of information concerning Sanofi's drugs that may affect the price of the Company's securities.

32. During the Class Period, the individual defendants specifically and repeatedly touted the safety profile of rimonabant, purportedly based on their access to, and knowledge of, safety data regarding rimonabant. The defendants routinely communicated with analysts and investors during the Class Period and represented that they were informed of and knowledgeable about rimonabant's efficacy, safety profile and the FDA approval process. ¶¶48-51, 54-56, 58, 63, 69, 72-73, 76. In the course of these communications, defendants presented detailed information regarding the drug. *Id.* Such information was available to the individual defendants, for purposes of presentation to analysts and investors, *vis-à-vis* their direct access to Sanofi's clinical trial safety database and possession of clinical trial Study Reports. Accordingly, defendants represented to the market that they had

intimate knowledge of these areas and responded to questions focused on the drug's efficacy, safety profile and the FDA regulatory process. At no time did any of the individual defendants respond that they were uninformed, or did not have access to material information concerning rimonabant.

Defendants' Role With Regard to FDA Approval Process of Rimonabant – Post February 17, 2006

33. Defendants submitted the rimonabant NDA to the FDA in April 2005 seeking approval of rimonabant as an obesity treatment. The NDA reported only one case of suicidal ideation in patients participating in the rimonabant trials, and that the patient had been taking a placebo, not rimonabant. When the FDA subsequently requested further information about suicidality in the rimonabant trials, Sanofi produced records of several additional cases of suicidal ideation in the rimonabant trials that had not been reported in the NDA. As a result of the signal between rimonabant and suicidality, on February 17, 2006, the FDA sent defendants a letter asking them to reassess the database from the rimonabant trials and investigate the link between the drug and suicidality. As the FDA put it, "review of the preclinical and clinical data raised concern about associations between rimonabant and increased frequencies of psychiatric adverse events, including suicidality." The FDA further directed Sanofi to obtain a formal assessment of a possible link between rimonabant and suicidality from Dr. Posner, a leading suicide researcher at Columbia University.

34. During the Class Period, defendants spoke repeatedly about the contents of the February 2006 letter from the FDA. *See, e.g.*, ¶¶51, 55, 58, 66. As such, they either were aware of the contents of that letter or reckless in speaking about it.

35. Based on Sanofi's data, Dr. Posner's assessment showed a statistically significant link between rimonabant and suicidality. Defendants submitted Dr. Posner's findings to the FDA on October 26, 2006. That submission showed a statistically significant link between rimonabant and